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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,583	11/28/2000	Christiaan M. Saris	MBHB00-1213	9474

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	6

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/724,583	Saris et al.
Examiner	**Art Unit**
Prema Mertz	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 21, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-56* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-4. Claims 1-8, 10-11, 42-46, are drawn to a polynucleotide encoding an IL-1 receptor antagonist-like polypeptide as set forth in SEQ ID NO:2, 4, 6 or 36, a vector, a host cell and a process for producing the polypeptide, classified in Class 435, subclass 69.1.

Groups 5-8. Claims 18-32, 34-35 are drawn to antibody to an IL-1 receptor antagonist-like polypeptide as set forth in SEQ ID NO:2, 4, 6 or 36, classified in Class 530, subclass 387.1.

Groups 9-12. Claims 9, 13-17, 37-41, 55-56 are drawn to an IL-1 receptor antagonist-like polypeptide as set forth in SEQ ID NO:2, 4, 6 or 36, classified in Class 530, subclass 350.

Groups 13-16. Claim 47 is drawn to a method of treatment by administering the IL-1 receptor antagonist-like polypeptide as set forth in SEQ ID NO:2, 4, 6 or 36, classified in Class 514, subclass 2.

Groups 17-20. Claims 36, 48 is drawn to a method of diagnosing a condition by determining the presence of the IL-1 receptor antagonist-like polypeptide as set forth in SEQ ID NO:2, 4, 6 or 36, classified in Class 435, subclass 7.1.

Groups 21-24. Claim 49 is drawn to a device comprising cells secreting the IL-1 receptor antagonist-like polypeptide as set forth in SEQ ID NO:2, 4, 6 or 36, Class and subclass undeterminable.

Groups 25-28. Claims 12, 50-51, are drawn to a method of identifying a compound which binds to the IL-1 receptor antagonist-like polypeptide as set forth in SEQ ID NO:2, 4, 6 or 36, classified in Class 435, subclass 7.2.

Groups 29-32. Claim 52 is drawn to a method of treatment by administration of DNA encoding IL-1 receptor antagonist-like polypeptide as set forth in SEQ ID NO:2, 4, 6 or 36, classified in Class 514, subclass 44.

Groups 33-36. Claim 53 is drawn to a transgenic non-human animal comprising the nucleic acid encoding IL-1 receptor antagonist-like polypeptide as set forth in SEQ ID NO:2, 4, 6 or 36, classified in Class 800, subclass 21.

Groups 37-40. Claim 33 is drawn to a method of treating a disease by administering the antibody to the IL-1 receptor antagonist-like polypeptide as set forth in SEQ ID NO:2, 4, 6 or 36, classified in Class 424, subclass 139.1.

Groups 41-44. Claim 54 is drawn to a method of identifying a compound which binds to the IL-1 receptor antagonist-like polypeptide as set forth in SEQ ID NO:2, 4, 6 or 36, by using a transgenic non-human mammal classified in Class 435, subclass 7.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-4, 5-8, 9-12, 21-24 and 33-36 are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The polynucleotides of inventions 1-4 can be used to make hybridization probes or can be used in gene

therapy as well as in the production of the proteins of interest. The protein of invention 9-12 can be used as a probe, or used therapeutically or diagnostically, e.g. in screening. The antibodies of inventions 5-8 can be used to obtain the polynucleotides of Groups 1-4, and can also be used in diagnostics, e.g. as a probe in immunoassays. The polynucleotide of Group 1 can only be used to obtain the protein of Group 9 and not Groups 10-12, while the polynucleotide of Group 4 can only be used to obtain the protein of Group 12, not the proteins of Groups 9-11.

Inventions 1-4 and 9-12 are related as processes of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the proteins can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions 1-4 and 29-32, 33-36 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products as claimed can be used as a hybridization probes.

Inventions 9-12 and 13-16, 21-24, 25-28 are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions 9-12 can also be used as antigens in the production of antibodies.

Inventions 5-8 and 17-20, 37-40, are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions 5-8 can also be used in immunochromatography.

Inventions 1-4 and 29-32, 33-36, 37-40, are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions 1-4 can also be used in the production of the specific recombinant proteins.

Inventions 33-36 and 41-44, are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case the products of inventions 33-36 can also be used in the production of the specific recombinant proteins.

Inventions I-4 and 13-16, 17-20, 21-24, 25-28, 37-44 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 5-8 and 13-16, 21-24, 25-36, 41-44 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 9-12 and 17-20, 29-44 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 21-24 and 13-20, 25-44 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions 13-44 are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Election of species:

This application contains claims directed to the following patentably distinct species of the claimed invention: as recited in claims 55-56.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 55-56 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of

an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Patent Examiner
Art Unit 1646
February 27, 2002